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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/882,505

06/15/2001

Mark L. Nelson

GAZ-057

8352

959

7590

08/07/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/07/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/882,505

Applicant(s)

NELSON ET AL.

Examiner

Barbara P Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-31 is/are allowed.
- 6) ☐ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

First Office Action on the Merits

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-4, 9, 10, 27 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Koza.

Koza teaches 7-substituted tetracycline derivatives such as 7-phenylsancycline, 7-(4-fluorophenyl)sancycline and 7-(4-chlorophenyl)sancycline (see the entire article, especially page 816, Table 1, compound #s 1-4). The compounds taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koza.

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Koza teaches 7-substituted tetracycline derivatives such as 7-phenylsancycline, 7-(4-fluorophenyl)sancycline and 7-(4-chlorophenyl)sancycline (see the entire article, especially page 816, Table 1, compound #s 1-4).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. For example, claims 5-8 recite the claimed compounds having a 2- or 3-substituted phenyl substituent attached to the 7-position.

The compounds of claims 5-8 are positional isomers of the prior art compounds and, thus, are unpatentable unless they possess some unobvious or unexpected beneficial property not possessed by the prior art compounds. In re Norris, 179 F.2d 970, 84 USPQ 458 (CCPA 1970). The motivation to make positional isomers of the prior art compounds is based on the close structural similarity of the compounds and the expectation in the art that positional isomers would have similar properties.

Claims 11-26 differ from the reference by reciting treatment of a tetracycline responsive state such as bacterial infection. However, tetracycline and its derivatives are known broad-spectrum antibiotics useful against a vast number of bacterial infections (see Koza page 815, 1st paragraph). Thus, the use of any tetracycline derivative, including those taught by Koza and recited by the instant claims, in treating bacterial infections would be prima facie obvious. The motivation to use these compounds as recited by the instant invention would be based on the knowledge of the skilled artisan in the art and, thus, the expectation that any tetracycline derivative would be useful in treating tetracycline responsive disease states including bacterial infections.

Allowable Subject Matter


5. Claims 29-31 are allowed.

Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
August 1, 2002